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Spine 360 Anterior Cervical Plate System

510(k) Summary of Safety and Effectiveness

SUBMITTED BY	Spine 360 5000 Plaza on the Lake, Suite 305 Austin, Texas 78746 Phone: 512-772-4442 Fax: 800-640-6045
ESTABLISHMENT REGISTRATION NUMBER	3005841736
CONTACT PERSON	Tim Hildebrand Project Manager Phone: 512-772-3774 Fax: 800-640-6045
SUBMISSION PREPARED BY	Lisa Peterson Kaedon Consulting, LLC Phone: 512-507-0746
DATE PREPARED	August 11, 2009
CLASSIFICATION	KWQ 888.3060- Spinal Intervertebral Body Fixation Orthosis
COMMON NAME	Spinal Fixation System
PROPRIETARY NAME	Spine 360 Anterior Cervical Plate System
SUBSTANTIAL EQUIVALENCE	The Spine 360 ACP System was determined to be substantially equivalent to the Synthes CSLP predicate device.

DEVICE DESCRIPTION

The Spine 360 anterior cervical plates are provided preassembled and are offered with fixed angle bone screws. The system consists of four (4) primary components: 1) anterior plate, 2) self-tapping fixed angle bone screws, 3) locking shield screws and 4) locking shield.

INDICATIONS:

The Spine 360 Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) as an adjunct to fusion in the treatment of the following indications:

- Degenerative disc disease [DDD] – defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Spinal Stenosis
- Tumors
- Trauma (i.e. fracture)

MECHANICAL TEST DATA

Mechanical test results demonstrate that the Spine 360 ACP System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Spine 360
% Mr. Tim Hildebrand
Project Manager
5000 Plaza on the Lake, Suite 305
Austin, Texas 78746

Re: K092531
Trade/Device Name: Spine 360 Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: February 02, 2010
Received: February 03, 2010

Dear Mr. Hildebrand:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Buchner for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092531

Device Name: **Spine360 Anterior Cervical Plate System**

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092531

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